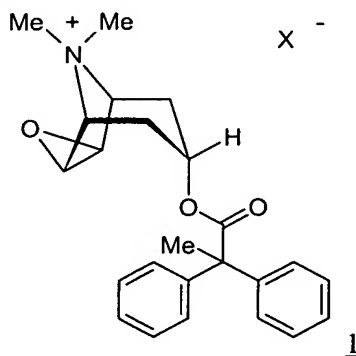


Amendments to the Claims

This listing of claims will replace all prior versions and listings of claims in the application:

1. (currently amended) A Pharmaceutical compositions, characterised in that they contain comprising:

(a) one or more anticholinergics of formula 1



wherein:

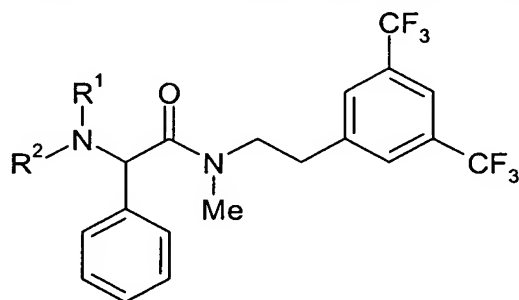
X⁻ denotes an anion with a single negative charge, preferably an anion selected from the group consisting of chloride, bromide, iodide, sulphate, phosphate, methanesulphonate, nitrate, maleate, acetate, citrate, fumarate, tartrate, oxalate, succinate, benzoate and p-toluenesulphonate; and

(b) combined with one or more NK₁ receptor antagonists (2), optionally in the form of or the enantiomers, mixtures of the enantiomers, or in the form of the racemates thereof, optionally in the form of the solvates, or hydrates thereof and optionally together with a pharmaceutically acceptable excipient.

2. (currently amended) The Pharmaceutical composition according to claim 1, wherein characterised in that in the compounds of formula 1 X⁻ is a negatively charged anion selected from the group consisting of chloride, bromide, iodide, sulphate, phosphate, nitrate, maleate, acetate, citrate, fumarate, tartrate, oxalate, succinate, benzoate, 4-toluenesulphonate, and/or methanesulphonate.

3. (currently amended) The Pharmaceutical composition according to claim 1, ~~characterised in that in the compounds of formula 1 wherein X⁻ denotes~~ bromide.

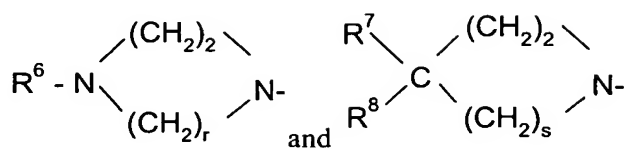
4. (currently amended) The Pharmaceutical composition according to claim 1, ~~wherein characterised in that 2~~ the NK₁ receptor antagonists ~~is~~are selected from among-BIIF 1149, CP-122721, FK-888, ~~NKP-608C~~, NKP 608A, CGP 60829, SR 48968 (Saredutant), SR 140333 (Nolpitantium besilate/chloride), LY 303—870 (Lanepitant), MEN-11420 (Nepadutant), SB 223412, MDL-105172A, MDL-103896, MEN-11149, MEN-11467, DNK 333A, SR-144190, YM-49244, YM-44778, ZM-274773, MEN-10930, S-19752, Neuronorm, ~~YM-35375~~, DA-5018, MK-869, L-754030, CJ-11974, L-758298, DNK-33A, ~~6b-I~~, CJ-11974, TAK-637, GR 205171, N-[2-(3,5-bis-trifluoromethyl-phenyl)-ethyl]-2-{4-[(3-hydroxy-propyl)-methyl-amino]-piperidin-1-yl}-N-methyl-2-phenyl-acetamide, N-[2-(3,5-bis-trifluoromethyl-phenyl)-ethyl]-2-[4-(2-hydroxy-1-hydroxymethyl-ethylamino)-piperidin-1-yl]-N-methyl-2-phenylacetamide, N-[2-(3,5-bis-trifluoromethyl-phenyl)-ethyl]-2-[4-(cyclopropylmethyl-methyl-amino)-piperidin-1-yl]-N-methyl-2-phenyl-acetamide, N-[2-(3,5-bis-trifluoromethyl-phenyl)-ethyl]-2-{4-[(2-hydroxy-ethyl)-(3-hydroxy-propyl)-amino]-piperidin-1-yl}-N-methyl-2-phenyl-acetamide, N-[2-(3,5-bis-trifluoromethyl-phenyl)-ethyl]-2-{4-[cyclopropylmethyl-(3-hydroxy-propyl)-amino]-piperidin-1-yl}-N-methyl-2-phenyl-acetamide, ~~and theor an~~ arylglycinamide ~~compound~~derivatives of general formula 3



3

wherein:

R¹ and R² together with the N to which they are bound form a ring of formula

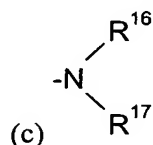


wherein r and s are each 2 or 3;

R^6 ~~denotes~~ is H, -C₁-C₅-alkyl, C₃-C₅-alkenyl, propynyl, hydroxy(C₂-C₄)alkyl, methoxy(C₂-C₄)alkyl, di(C₁-C₃)alkylamino(C₂-C₄)alkyl, amino(C₂-C₄)alkyl, amino, di(C₁-C₃)alkylamino, monofluoro- to perfluoro(C₁-C₂)alkyl, N-methylpiperidinyl, pyridyl, pyrimidinyl, pyrazinyl, or pyridazinyl,

R^7 ~~has~~ is one of the meanings (a) to (d),

- (a) hydroxy,
- (b) 4-piperidinopiperidyl,



wherein R^{16} and R^{17} are each independently ~~of each other denote~~ H, (C₁-C₄)alkyl, (C₃-C₆)cycloalkyl, hydroxy(C₂-C₄)alkyl, dihydroxy(C₂-C₄)alkyl, (C₁-C₃)alkoxy(C₂-C₄)alkyl, phenyl(C₁-C₄)alkyl, or di(C₁-C₃)alkylamino(C₂-C₄)alkyl, and

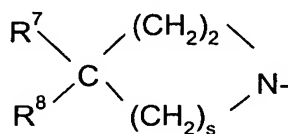
R^8 ~~denotes~~ is H,

~~optionally in the form of the or an~~ enantiomers, ~~and mixtures of enantiomers thereof,~~
~~optionally in the form of the or~~ racemates thereof.

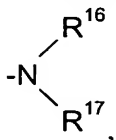
5. (currently amended) The ~~P~~pharmaceutical composition according to claim 1, ~~wherein characterised in that 2~~ NK₁ receptor antagonists ~~is are~~ selected from the group consisting of BIIF 1149, CP-122721, CGP 60829, MK-869, CJ-11974, GR 205171, N-[2-(3,5-bis-trifluoromethyl-phenyl)-ethyl]-2-[4-[(3-hydroxy-propyl)-methyl-amino]-piperidin-1-yl]-N-methyl-2-phenyl-acetamide, N-[2-(3,5-bis-trifluoromethyl-phenyl)-ethyl]-2-[4-(2-hydroxy-1-hydroxymethyl-ethylamino)-piperidin-1-yl]-N-methyl-2-phenylacetamide, N-[2-

(3,5-bis-trifluoromethyl-phenyl)-ethyl]-2-[4-(cyclopropylmethyl-methyl-amino)-piperidin-1-yl]-N-methyl-2-phenyl-acetamide, N-[2-(3,5-bis-trifluoromethyl-phenyl)-ethyl]-2-{4-[(2-hydroxy-ethyl)-(3-hydroxy-propyl)-amino]-piperidin-1-yl}-N-methyl-2-phenyl-acetamide, N-[2-(3,5-bis-trifluoromethyl-phenyl)-ethyl]-2-{4-[cyclopropylmethyl-(3-hydroxy-propyl)-amino]-piperidin-1-yl}-N-methyl-2-phenyl-acetamide, ~~and—theor~~ an arylglycinamide compoundderivatives of general formula 3, wherein:

R^1 and R^2 together with the N to which they are bound form a ring of formula



wherein s is 2 or 3,

 R^7 denotes a group is

wherein R¹⁶ and R¹⁷ are independently of each other denote H, (C₁-C₄)alkyl, (C₃-C₆)cycloalkyl, hydroxy(C₂-C₄)alkyl, dihydroxy(C₂-C₄)alkyl, (C₁-C₃)alkoxy(C₂-C₄)alkyl, phenyl(C₁-C₄)alkyl, or di(C₁-C₃)alkylamino(C₂-C₄)alkyl, and

R^8 -denotes is H ,

~~optionally in the form of the~~ an enantiomers, and mixtures of enantiomers, thereof and optionally in the form of the racemates thereof.

6. (currently amended) The Pharmaceutical compositions according to one of claim 1, ~~wherein~~ characterised in that 2 the NK₁ receptor antagonist is (S)-N-[2-(3,5-bis-trifluoromethyl-phenyl)-ethyl]-2-[4-(2-hydroxy-1-hydroxymethyl-ethylamino)-piperidin-1-yl]-N-methyl-2-phenylacetamide or an acid addition salt thereof.

7. (currently amended) The ~~P~~pharmaceutical composition according to claim 1, ~~characterised in that~~wherein the weight ratios of ~~1-the anticholinergic to 2-NK₁ receptor antagonist~~are in the range from 1:100 to 100:1, ~~preferably from 1:80 to 80:1.~~

8. (currently amended) The ~~P~~pharmaceutical composition according to claim 1, ~~characterised in that~~wherein a single administration corresponds to a dosage of the combination of ~~active substances 1-the anticholinergic and 2-the NK₁ receptor antagonist~~ of 0.01 μg to 10,000 μg , ~~preferably from 0.1 to 2,000 μg .~~

9. (currently amended) The ~~P~~pharmaceutical composition according to claim 1, ~~characterised in that~~wherein ~~it~~the pharmaceutical composition is in the form of a formulation suitable for inhalation.

10. (currently amended) The ~~P~~pharmaceutical composition according to claim 9, ~~wherein~~characterised in that it the pharmaceutical composition is a formulation selected from ~~among~~ inhalable powders, propellant-containing metering aerosols, and propellant-free inhalable solutions or suspensions.

11. (currently amended) The ~~P~~pharmaceutical composition according to claim 10, ~~characterised in that it~~wherein the pharmaceutical composition is an inhalable powder which contains ~~1the anticholinergic and 2-the NK₁ receptor antagonist~~ in admixture with suitable physiologically acceptable excipients selected from ~~among~~ the monosaccharides, disaccharides, oligo- and polysaccharides, polyalcohols, salts, or mixtures of these excipients.

12. (currently amended) The ~~I~~nhalable powder according to claim 11, ~~characterised in that~~wherein the excipient has a maximum average particle size of up to 250 μm , ~~preferably between 10 and 150 μm .~~

13. (currently amended) A ~~C~~capsule, ~~characterised in that it contains~~ing an inhalable powder according to claim 11 or 12.

14. (currently amended) The ~~P~~pharmaceutical composition according to claim 10, wherein the pharmaceutical composition~~characterised in that it is an inhalable powder consisting essentially of the NK₁ receptor antagonist~~which contains only active substances 1 and 2 as its ingredients.

15. (currently amended) The ~~P~~pharmaceutical composition according to claim 10, wherein the pharmaceutical composition~~characterised in that it is a propellant-containing inhalable aerosol comprising the anticholinergic~~which contains 1 and 2 the NK₁ receptor antagonist in dissolved or dispersed form.

16. (currently amended) The ~~P~~propellant-containing inhalable aerosol according to claim 15, ~~characterised in that it contains, as~~wherein the propellant gas is, hydrocarbons such as n-propane, n-butane, or isobutane, or halo~~hydrocarbons such as chlorinated and/or fluorinated derivatives of methane, ethane, propane, butane, cyclopropane, or cyclobutane.~~

17. (currently amended) The ~~P~~propellant-containing inhalable aerosol according to claim 16, ~~characterised in that~~wherein the propellant gas is TG11, TG12, TG134a, TG227, or a mixtures thereof.

18. (currently amended) The ~~P~~propellant-containing inhalable aerosol according to claim 15, ~~characterised in that it optionally contains~~further comprising one or more other ingredients selected from the group consisting of cosolvents, stabiliszers, surfactants, antioxidants, lubricants, and means for adjusting the pH.

19. (currently amended) The ~~P~~propellant-containing inhalable aerosol according to claim 15, ~~characterised in that it may~~wherein the inhalable aerosol contains up to 5 wt.-% of the anticholinergic active substance 1 and/or 2 the NK₁ receptor antagonist.

20. (currently amended) The ~~P~~pharmaceutical composition according to claim 10, ~~characterised in that it~~wherein the pharmaceutical composition is a propellant-free inhalable solution or suspension which contains water, ethanol, or a mixture of water and ethanol as solvent.

21. (currently amended) The ~~i~~nhalable solution or suspension according to claim 20, ~~characterised in that~~wherein the pH range is 2 -to 7, ~~preferably 2-5~~.

22. (currently amended) The ~~i~~nhalable solution or suspension according to claim 21, ~~wherein~~characterised in that the pH is adjusted by means of an acid selected from among hydrochloric acid, hydrobromic acid, nitric acid, sulphuric acid, ascorbic acid, citric acid, malic acid, tartaric acid, maleic acid, succinic acid, fumaric acid, acetic acid, formic acid, and propionic acid, or a mixtures thereof.

23. (currently amended) The ~~i~~nhalable solution or suspension according to claim 20, ~~characterised in that it optionally contains~~further comprising other co-solvents and/or excipients.

24. (currently amended) The ~~i~~nhalable solution or suspension according to claim 23, ~~characterised in that it contains as~~wherein the co-solvents ~~ingredients which contain hydroxyl groups or other polar groups, e.g. are~~ alcohols—particularly isopropyl alcohol, glycols—particularly propyleneglycol, polyethyleneglycol, polypropyleneglycol, glycolether, glycerol, polyoxyethylene alcohols, ~~and/or~~ polyoxyethylene fatty acid esters.

25. (currently amended) The ~~i~~nhalable solution or suspension according to claim 23, ~~characterised in that it contains as~~ wherein the excipients are surfactants, stabilizers, complexing agents, antioxidants and/or preservatives, flavourings, pharmacologically acceptable salts, ~~and/or~~ vitamins.

26. (currently amended) The ~~in~~halable solution or suspension according to claim 25, ~~characterised in that it contains as~~wherein the complexing agent is edietic acid or a salt of edietic acid, preferably sodium edetate.

27. (currently amended) The ~~in~~halable solution or suspension according to claim 25, ~~characterised in that it contains, as~~wherein the antioxidants, ~~compounds selected from among~~are ascorbic acid, vitamin A, vitamin E, ~~and~~or tocopherols.

28. (currently amended) The ~~in~~halable solution or suspension according to claim 25, ~~characterised in that it contains as~~wherein the preservatives ~~compounds selected from~~are cetyl pyridinium chloride, benzalkonium chloride, benzoic acid, ~~and~~or benzoates.

29. (currently amended) The ~~in~~halable solution or suspension according to claim 23, ~~consisting essentially of~~ characterised in that it contains, in addition to the active substances 1 and 2 the anticholinergic, the NK₁ receptor antagonist, and the solvent, only benzalkonium chloride, and sodium edetate.

30. (currently amended) The ~~in~~halable solution or suspension according to claim 23, ~~characterised in that it contains, in addition to the active substances~~ consisting essentially of 1 the anticholinergic, and 2 the NK₁ receptor antagonist, and the solvent, only and benzalkonium chloride.

31. (currently amended) The ~~in~~halable solution or suspension according to claim 20, ~~characterised in that it~~wherein the inhalable solution or suspension is a concentrate or a sterile ready-to-use inhalable solution or suspension.

32. (currently amended) A method of nebulizing the inhalable solution or suspension according to claim 20, in wherein the inhalable solution or suspension is nebulized using an inhaler according to WO 91/14468 or an inhaler as described in Figures 6a and 6b of WO 97/12687 ~~comprising providing an inhalable solution according to claim 20.~~

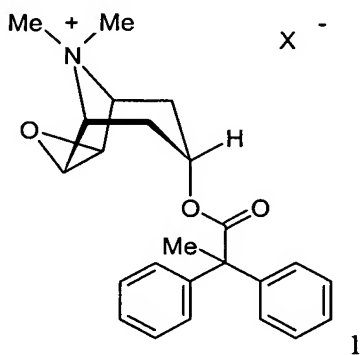
33. (currently amended) The method of nebulizing an inhalable solution or suspension according to ~~to~~ claim 31, ~~for nebulising in~~ wherein the inhalable solution or suspension is nebulized using an energy-operated free-standing or portable nebuliszer which produces inhalable aerosols by means of ultrasound or compressed air ~~according to the Venturi principle or other principles.~~

34. (currently amended) The Ppropellant-containing inhalable aerosol according to claim 17, ~~characterised in that~~ wherein the propellant gas is TG134a, TG227, or a mixture thereof.

35. (currently amended) A Method of treatment and/or prevention of an inflammatory or obstructive diseases of the respiratory tract comprising administering to a mammal in need of such a ~~treatment~~ a therapeutically effective amount of a pharmaceutical composition according to claim 1.

36. (currently amended) A kit comprising:

- (a) a first container containing a first pharmaceutical formulation comprising one or more anticholinergics of formula 1



wherein;

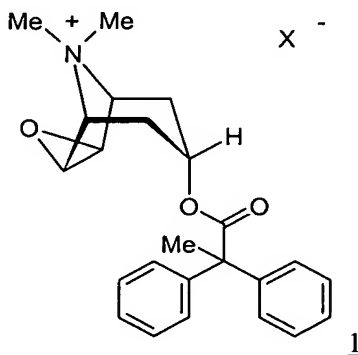
X⁻ ~~denotes~~ is an anion with a single negative charge, ~~preferably an anion selected from the group consisting of chloride, bromide, iodide, sulphate, phosphate, methanesulphonate, nitrate, maleate, acetate, citrate, fumarate, tartrate, oxalate, succinate, benzoate and p-toluenesulphonate,~~

~~optionally in the form of the or an~~ enantiomers, mixtures of the enantiomers, ~~or in the form of the racemates thereof, optionally in the form of the solvates, or hydrates and optionally together with a pharmaceutically acceptable excipient thereof;~~ and

(b) a second container containing a second pharmaceutical formulation comprising a one or more NK₁ receptor antagonists ~~(2), optionally in the form of the or an~~ enantiomers, mixtures of the enantiomers, ~~or in the form of the racemates thereof, optionally in the form of the solvates, or hydrates thereof;~~

~~each container each optionally further containing a pharmaceutically acceptable excipient.~~

37. (currently amended) A ~~M~~method of treatment and/or prevention of an inflammatory or obstructive diseases of the respiratory tract comprising administering simultaneously or sequentially to a mammal in need of such a treatment a therapeutically effective amount of ~~the~~ a first pharmaceutical formulation ~~(1)~~ comprising ~~one~~ or more anticholinergics of formula 1



wherein:

X⁻ ~~denotes~~ is an anion with a single negative charge, ~~preferably an anion selected from the group consisting of chloride, bromide, iodide, sulphate, phosphate, methanesulphonate, nitrate, maleate, acetate, citrate, fumarate, tartrate, oxalate, succinate, benzoate and p-toluenesulphonate,~~

and a second pharmaceutical formulation comprising one or more NK₁ receptor antagonists (2),

each ~~of (1) the anticholinergic and (2) the NK₁ receptor antagonist~~ optionally in the form of ~~an~~ the enantiomers, mixtures of ~~the enantiomer enantiomers, s or in the form of the racemates~~

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Reply dated November 30, 2004
Reply to Office Action dated June 3, 2004

~~thereof, optionally in the form of the solvates, or hydrates thereof and optionally together
with a pharmaceutically acceptable excipient;
wherein the first and second pharmaceutical formulations are administered simultaneously or
separately.~~